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| 10/657,907 | 09/09/2003 | Mark A. Reiley | 9448.17205-CIP DIV 5 | 5636 |
| 66854 | 7590 | 10/29/2007 | | |
| SHAYGLENN LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403 | | | EXAMINER ISABELLA, DAVID J | |
| | | | ART UNIT 4156 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/657,907

Applicant(s)

REILEY, MARK A.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> 8/14/07 | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adapted and configured" in the claims is a relative term which renders the claim indefinite. The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language absent structural features relies solely on a functional use (ie. to replace a certain anatomical feature. The elected invention is directed to figure 24 and description of the elected illustrated device is found on pages 22-25 of the specification. Claim 1 positively sets forth structural elements of a body and a facet joint structure.

1. (Original) *A prosthesis to replace a natural articular process of a natural facet joint on a vertebral body comprising a **prosthesis body** accommodating fixation to the vertebral body at or near a pedicle and without support by a lamina, and **an artificial facet joint structure** carried by the prosthesis body adapted and configured to replace a natural articular process of a natural facet joint.*

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However, claim 2 fails to positively set forth structure that would function after the removal of at least some of the lamina from the vertebral body. It is not clear from

Claim 1 is directed to a prosthesis system comprising:

A caudal prosthesis that may be fixed at or near a pedicle. The caudal prosthesis includes a joint structure. The system further includes a cephalad prosthesis that may be fixed to the superior vertebral body at or near a pedicle. The cephalad prosthesis includes a joint structure that is to articulate with the caudal prosthesis.

Claim 2 is presented below:

2. (Original) A prosthesis according to claim 1 wherein the artificial facet joint structure is adapted and configured to replace a natural articular process of a natural facet joint after removal of at least some of a lamina from the vertebral body.

It is not clear how the structure of the device is further defined (as illustrated in elected figure 24) by the function of "adapted and configured to replace a natural articular process". It appears that the structure as set forth in claim 1 and as illustrated in figure 24 is not further modified by the method steps of claim 2. In fact, it appears that the device as shown in figure 24 is utilized in each method as claimed in claims 1 and claim 2, respectively. (i.e. how does the structure of claim 2 differ from the structure of claim 1?).

The same questions of indefiniteness are also applicable with respect to claims 3-17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Wall [4633722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486]

The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language, absent structural features, relies solely on a functional use (ie. to replace a certain anatomical feature). It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some portion of the various anatomical structures as set forth in claims 2-26

Each reference illustrates a prosthesis that includes a prosthesis body for fixation to an anatomical bone structure and an artificial joint structure carried by the prosthesis body. In each instance, the devices are capable of performing the function as broadly set forth in the claims.

With respect to claims 18 and 19, each device is made from a medical material from the group of known materials.

Response to Arguments

Applicant's arguments filed 12/18/2006 have been fully considered but they are not persuasive.

Applicant's claims are directed to illustrated figure 24. The figure shows only one configuration, yet applicant maintains that the language of "adapted and configured" further defines the structure according to how the prosthesis is surgically implanted. Frankly, it remains unclear how the device as "adapted and configured to replace a natural articular process of a natural facet joint after removal of at least some of a lamina from the vertebral body" as set forth in claim 2, is structurally different than, for example only, the joint structure that is "adapted and configured to replace a natural articular process of a natural facet joint after removal of at least some of the natural articular process from the vertebral body", as set forth in claim 6. It appears that if the claims, in fact, are readable on the elected figure 24, there is only one embodiment that would perform all the surgical steps as set forth in each of claims 2-17. In fact, it appears that the structure is not further modified i.e. "adapted and configured" to meet the surgical constraints in each method step as set forth in claims 2-17.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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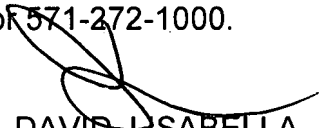
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
7/13/2007